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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,811	07/31/2001	Roni Zvuloni	00/20827	9492

7590

11/19/2002

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EXAMINER

VRETTAKOS, PETER J

ART UNIT

PAPER NUMBER

3739

8

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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condo docs

# Office Action Summary

Application No.

09/917,811

Applicant(s)

ZVULONI ET AL.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, Claims 1-33 in Paper No. 7 is acknowledged.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

The corrected or substitute drawings were received on 10-17-01. These drawings are acceptable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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Claims 1-3 and 5-15 are rejected under 35 U.S.C. 102(e) as being anticipated by LePivert ('018).

Independent claim 1

LePivert discloses a planning system (fig. 5) for planning a cryosurgical ablation procedure, comprising: a first imaging modality (100) for creating digitized (col. 6:62) preparatory images of an intervention site (col. 3:41-45); a three dimensional modeler (104) for creating a three dimensional model of the intervention site based on the digitized preparatory images; and a simulator (col. 3:38-40) for simulating a cryosurgical intervention, which comprises an interface (150) useable by an operator for specifying loci for insertion of cryoprobes (106) and operational parameters (col. 8:27-31) for operation of cryoprobes for cryoablating tissues; and a displayer (108) for displaying in a common virtual space an integrated image comprising a display (col. 8:13-14) of the three dimensional model of the intervention site and a virtual display (anatomic image, col. 8:15) of cryoprobes inserted at the loci (also read col. 7 lines 7-10).

Dependent Claims

Re: claim 2, LePivert discloses a memory for storing ("recording") loci for insertion and operational parameters (col. 3:16-22, 41-45).

Re: claim 3, LePivert implicitly discloses a method of computerized tomography imaging (impedance measurements to create a digitized image, col. 4: 58-59). Also, MRI and ultrasound imaging is disclosed (col. 2: 64-67).

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Re: claims 5-10, LePivert discloses the ability to highlight selected (ex. eutectic, non-eutectic) regions within the 3-D model (col. 4:54-57). LePivert also discloses markers (col. 6: 67) for the images generated by the MRI or ultrasound devices allowing the modeler (104) to subsequently generate images of the "eutectic zone" or the tissue to be cryoablated, as well as the tissue to be protected. Note column 7 lines 5-10.

Re: claims 11-15, LePivert discloses in figure 1, different zones (surrounding the cryoprobe 10) of relevance to the operation. For example, zone 1 depicts a hypothetical zone of complete freezing. The demarcation of zones by LePivert in figure 1 is equivalent to disclosing a predictor for predicting probe effects on tissue. LePivert is able to define the specific dimensions of the disclosed zones in figure 1 for each surgery, thereby allowing the operator to better control the destruction of targeted tissue while preserving non-targeted tissue. Incomplete freezing zones (2) are also submitted, which allows for prediction of less-than total destruction of tissues within a said volume of desired total destruction of tissues as defined by an operator.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over LePivert.

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LePivert discloses in col. 3: 43-45, "the information (from the computerized images) used to control the placement and operation of the cryoprobe." This specific disclosure indicates that the images provide a *recommended* course of action for the impending surgery. The recommended course of action would obviously include parameters such as the optimal number of cryoprobes, temperature, duration of cooling, specific locations for insertion, etc.

Re: claim 4: the use of a Cartesian coordinate system to express a 3-D model is a ubiquitous act throughout the scientific modeling community in the majority of fields, including medicine.

Therefore, at the time of the invention it would have been obvious to modify LePivert by including as a design expedient the ability to acquire important operational parameters. The motivation would be to improve the efficacy of the device and the surgery.

Claims 23, 24, 25, 27-30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over LePivert in view of Mikus et al. ('690).

LePivert neglects to disclose cryosurgical prostate treatment.

Mikus et al. discloses, *inter alia*, a cryosurgical prostate treatment (col. 1:15-18; col. 2:57). Also disclosed is *percutaneous* prostate cryoablation (col. 3:56).

Therefore, at the time of the invention it would have been obvious to modify LePivert in view of Mikus et al. by including as protocol treatment for the prostate. The

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motivation would be to provide an additional application for the LePivert ablation system.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over LePivert in view of Mikus et al. ('690) and further in view of Crockett ('488).

LePivert and Mikus neglect to explicitly disclose *transperineal* cryosurgical prostate treatment (col. 3: 65-67).

Crockett discloses *transperineal* cryosurgical prostate treatment.

Therefore, at the time of the invention it would have been obvious to modify LePivert in view of Mikus et al. and further in view of Crockett by including as protocol *transperineal* treatment for the prostate. The motivation would be to provide an additional application for the LePivert ablation system.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over LePivert in view of Mikus et al. ('690) and further in view of Fenn et al. ('426).

LePivert and Mikus neglect to explicitly disclose the use of AUA scores in conjunction with prostate cryoablation.

Fenn et al. discloses the use of AUA scores in conjunction with prostate cryoablation.

Therefore, at the time of the invention it would have been obvious to modify LePivert in view of Mikus et al. and further in view of Fenn et al. by including AUA

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scores in the protocol. The motivation would be to provide better treatment by using a commonly used indicator of prostate tissue health.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos  
November 11, 2002

*PV*

*Roy D. Gibson*  
**ROY D. GIBSON**  
**PRIMARY EXAMINER**